

SECTION 14**SMDA SUMMARY
for Safety and Effectiveness**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the written requirements of SMDA 1990 and 21 CFR 807.92

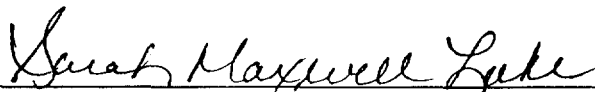
SAFETY AND EFFECTIVENESS OF THE *MUSCLE WAND*™

These proposed changes to an already approved and marketed device does in no way alter the safety and effectiveness of this medical device. The Thera-Cane k903820 predicate device has a proven track record that establishes this product line as safe to the physical therapy patient. The modifications of design change of "S" shape, adding roller beads and handles, adding interchangeable massage balls and adding a collapsible feature does not change the safety or effectiveness of this device.

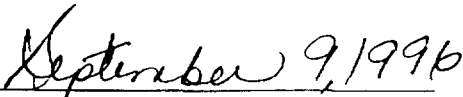
The proposed product is identical in intended use, materials, anatomical sites, target population, physical safety, biocompatibility and performance to the predicate device stated. Any modification made to the proposed device does not alter safety or effectiveness.

OTC Determination for this type of device has been proven safe to the consumer. The predicate device has been sold OTC since 1990 and has been proven to be an asset to the patient experiencing muscle spasm and/or muscle tension.

No claims are made implying cure. This device is used in the treatment and management of muscle spasm and muscle tension.



Sarah Maxwell Lake, Regulatory Affairs
Shippert Medical Technologies Corporation



Date

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